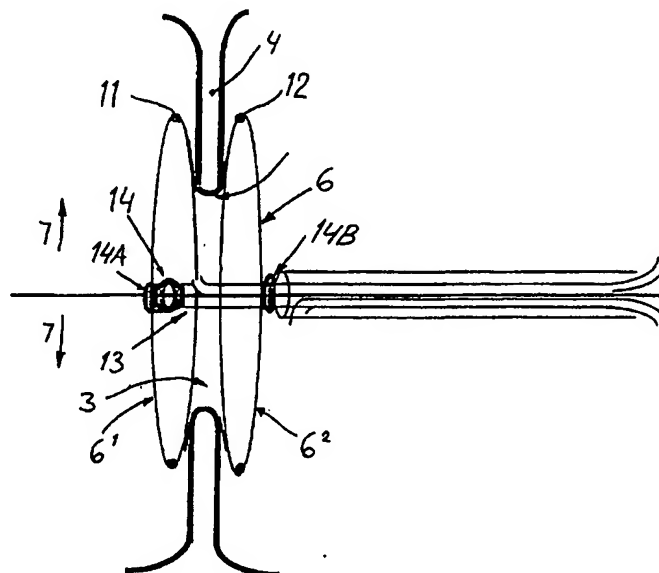




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(21) International Application Number: PCT/SE97/00747 (22) International Filing Date: 6 May 1997 (06.05.97) (30) Priority Data: 9601752-0 8 May 1996 (08.05.96) SE (71) Applicant (for all designated States except US): CARDIAC SERVICE HB [SE/SE]; Humlekärret 6, S-427 36 Billdal (SE). (72) Inventor; and (75) Inventor/Applicant (for US only): SOLYMAR, Laszlo [SE/SE]; Humlekärret 6, S-427 36 Billdal (SE). (74) Agent: CEGUMARK AB; P.O. Box 53047, S-400 14 Göteborg (SE).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Swedish).</i>

(54) Title: A DEVICE FOR PLUGGING AN OPENING IN A WALL OF A HOLLOW OR TUBULAR ORGAN

**(57) Abstract**

The present invention relates to a device (1) at an implant (2) for closing a passage (3), as e.g. an aperture through the auricle diaphragm (4) or the ventricle diaphragm of a heart or in a body channel and comprising a closing body (6; 106) which is fixable at the passage (3). According to the invention, a fluid tight closing body (6; 106) which is expanding and stiffening in a radial direction (7; 107) is arranged to be built up at the position (9; 109) of the intended closing spot, after insertion through a body vein.

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A DEVICE FOR PLUGGING AN OPENING IN A WALL OF A HOLLOW OR TUBULAR ORGAN

5 The present invention relates to a device at an implant for closing a passage as e.g. an aperture through the auricle diaphragm or the ventricle diaphragm of a heart or in a body channel, and comprising a closing body which is fixable at the passage.

10 By means of EP,B1, 0 362 113 it is previously known a device for closing a passage in the heart of patients, wherein the closing part run the risk of tipping over and thereby causing the passage to be exposed for passing through the heart. The cause of the insecure closing capacity is the insecure
15 manoeuvrability for the closing part when applied around the passage and that the application takes part long before it has arrived on its final position around the passage in the heart.

 The main object of the present invention is therefore primarily to try to solve the described problem with manoeuvra-
20 bility and application.

 Said object is achieved by means of a device according to the present invention, which is substantially characterized in that a fluid tight closing body which is expanding and stiffening in a radial direction is arranged to be built up at
25 the position of the intended closing spot, after insertion through a body vein.

 The invention will be described here below as a number of preferred embodiments, wherein reference is made to the accompanying drawings, in which

30 Fig 1 shows a section through a heart during application of the implant in it,

Fig 2 shows the implant positioned in the heart,
Fig 3-5 a first embodiment of an implant wherein,
Fig 3 shows the implant moved into position before
fixing,

5 Fig 4 shows the implant below a fixing position,
Fig 5 shows the implant in its fixing position,
Fig 6 shows application of a spiral thread via
sheaths, and

Fig 7-9 shows a second embodiment of an implant,
10 wherein

Fig 7 shows an initial position for said implant seen
from the side and from one end respectively,

Fig 8 shows said implant at a between position during
extension seen from the side and one end respectively,

15 Fig 9 shows the implant completely extended seen from
the side and one end respectively,

Fig 8A shows the implant in a perspective view during
extension,

Fig 9A shows an end view of the implant in its
20 extended position, and

Fig 10 shows schematically the principle for building
up the hub and connection of the implant to it and the final
position of the implant in completely extended condition seen
from the side.

25 The invention relates to a preferably cardiological
implant by means of which it is possible e.g. to close an
aperture through the auricle diaphragm or the ventricle
diaphragm of a heart.

The implant according to the present invention is
30 arranged to be built up at the location in the body e.g. the
heart, in contrast to known implant e.g. so called umbrellas and

sails that are instead extended as soon as the compressed umbrella leaves its insertion sheath.

According to the invention which concerns a device 1 at an implant 2 for closing an internal passage 3, like e.g. an aperture in the auricle diaphragm 4 or the ventricle diaphragm of a heart 5 or in a desired body channel which one wishes to close, it concerns a closing body 6 which is to be built up at the location. More exactly, an embodiment of the invention which is shown on the drawings in Fig 1-5, is formed by a in radial direction 7 expanding and stiffening fluid tight closing body 6. This body 6 is arranged to be built up at the position 9 of the intended closing spot, after insertion through a body vein 8.

Said closing body 6 consists of an inflatable balloon, preferably double balloon of thin and non-thrombogenic material. A connection part 10 between the two balloon elements 6A, 6B is arranged to form a guidance for the two balloon elements 6A, 6B around the peripheral edge 3A of said aperture 3.

Both chambers 6A, 6B of the balloon 6 are arranged to be dilated radially 7 by means of a number of stiffening means 11, 12 which in the first shown example is realised in the shape of a coil spring which in each case is received in the respective balloon chamber 6¹, 6², in order to dilate said balloon chamber 6¹, 6² radially in the operational position and thereby bring about an efficient holding of the balloon around the aperture 3, as is shown in Fig 4.

A centrally, at the middle 13 of the balloon located locking mechanism 14 is arranged mutually interconnect both balloon chambers 6¹, 6² at their central part. Suitably, the aforementioned locking mechanism 14 is divided into two with each respective locking member 14A, 14B attachable to the outer wall 6C, 6D of the respective balloon chamber 6¹, 6². For

example, the aforementioned locking members 14A, 14B may be of a prior art type, e.g. as snap together members.

The described implant 2 is delivered to the location for application in the form of a tightly over an inner sheath 15 rolled up double balloon, 6 of thin, durable and physically friendly non-thrombogenic material. Two narrow delivery catheters 16, 17 extend through said inner sheath 15 of which the distal delivery catheter 16 has its outlet opening 18 in the distal balloon 6¹ and in a corresponding manner, the proximal catheter 17 has its outlet opening 19 in the proximal balloon 6²:

By means of the well known Seldinger technique, a vein inserter of dimension 11 F is inserted into the femoral vein. A catheter is placed in the left upper pleural vein and through this is passed a conductor 20 which is left behind for subsequent implant work. At the same time, this constitutes a part of a safety system against unintentional release, because the conductor 20 locks the fastening mechanism between the inner sheath 15 and the implant 2. Over the conductor 20, the implant 2 is introduced into the vein inserter, then in the lower vena cava and further up to the heart 5 until the central mark reaches the middle of the aperture 3 or any other defect which is desired to be closed. After that, the distal balloon 6¹ is filled with contrast fluid via the distal delivery catheter 16, whereupon the intended metal spiral 11 is inserted into the delivery catheter 21 and is fed in until it rolls itself up inside the distal balloon 6¹. In a corresponding way, the proximal balloon 6² is filled with contrast fluid in order to enable the parts to be visible via roentgen inside the body during the work to move them into position. After that a metal spiral 12 is also delivered to the proximal balloon 6², as is shown in Fig 3. So when the metal spirals 11, 12 or other as

stiffeners functioning means are located in the correct position, they are released by backing the constraining mandrins out of the metal spirals 11, 12. The contrast fluid 22, 23 is evacuated out from the balloons 6¹, 6² and the distal part 14 of the locking mechanism is pulled through its proximal ring 14B in the locking position. The conductor 20 is then pulled out accompanied by the inner sheath 15 which now runs freely and is pulled out from the distal balloon attachment and also the outer enclosing delivery sheath 24.

10 The embodiment which is shown in Fig 7-10 departs from the above described first embodiment, foremost by instead of using metal spirals as dispersing force which maintains a balloon or other occluding sail in position, utilising the rotating quality of non-bendable metals when they are bent, and
15 when the ends move past a critical point. For this object, there are thin nitinol treads attached around an inner core for example in each end for example inside a balloon according to the above. The distal and the proximal balloons has a further opening between them and the diameter of the balloon at its
20 smallest part corresponding to the ASD-size, i.e. that it is somewhat but not much larger. The balloons are inflated by means of a contrast fluid whereupon the furthestmost, as seen in the direction of insertion, attachment point of the nitinol threads are slowly pulled back at the same time as the nearest, as seen
25 in the direction of insertion, are pushed ahead, i.e. in the direction toward each other. At a critical position, the threads are twisted sideways and maintains a circular shape, which desired shape is used according to the present invention. In position, the balloons are evacuated and the threads are locked
30 in the twisted spring-like position.

More precisely, with reference to said figures 7-10 are formed a device 101 at an implant for closing a passage, for example according to the above described embodiment, and which comprises a closing body 106 which is attachable at said
5 passage, alone or in combination with further sealing means in a radial direction 107 expanding stiffening fluid tight closing body. Said body 106 is arranged that after insertion through a not shown body vein in its longitudinal direction 150, to be built up at the position 109 for the intended closing spot.

10 A number of threads 151 which in the shown embodiment are eight in number are arranged of such a material and with such qualities that they twist automatically sideways to form a circular shape, as is shown in Fig 9 and are locked in the twisted coil-like position for interconnecting the two balloon
15 chambers etc. against each other. The body 106 is preferably formed by a plurality of thin nitinol threads which are attached to a respective in axial direction 150, 152 relative to each other movable holder nuclei 153, 154. The threads 151 are arranged to twist sideways in the same direction and then to
20 assume a circular shape 155, similar to a flower, a propeller or an umbrella with circular shape and arranged with suitable means for closing said passage, e.g. that layers of be watertight material are connected to the threads 151.

In the example according to Fig 10 is shown how the
25 threads 151 are attached with different inclination x , y with reference to the respective separate holder nuclei 156, 157. For this object, the threads 151 are arranged to be mutually forced to be directed toward that holder nucleus 157 from which the threads 151 depart with the largest angle y , as calculated from
30 the centre axis 158 of the holder nuclei, with similar angle z for the different threads 151.

The invention has been carefully described in the above mentioned example and therefore the idea should be clearly understood and the invention is neither limited to the above described and on the drawings shown embodiment, but may be
5 varied within the scope of the claims without departing from the concept of the invention.

C l a i m s

- 5 1. A device (1; 101) at an implant (2) for closing a passage (3), as e.g. an aperture through the auricle diaphragm (4) or the ventricle diaphragm of a heart or in a body channel and comprising a closing body (6; 106) which is fixable at the passage (3), **characterized in** that a fluid tight closing body
10 (6; 106) which is expanding and stiffening in a radial direction (7; 107) is arranged to be built up at the position (9; 109) of the intended closing spot, after insertion through a body vein.
2. A device according to claim 1, **characterized in** that the closing body (6) consists of an inflatable balloon of thin
15 and non-thrombogenic material.
3. A device according to claim 2, wherein the closing body (6) is formed by a cardiological implant (2) for closing an aperture (3) in a diaphragm wall (4) in a heart (5),
characterized in that the balloon (6) is formed by a double bal-
20 loon at which a connection part (10) between the two balloon elements (6A, 6B) is arranged to form a guidance for the two balloon elements (6A, 6B) around the circumference edge (3A) of said aperture (3).
4. A device according to claim 3, **characterized in** that
25 both chambers (6¹, 6²) of the balloon (6) are arranged to be dilated radially (7) by means of a stiffening means (11, 12).
5. A device according to claim 4, **characterized in** that a stiffening means (11, 12) in the shape of a coil spring is received in the respective balloon chamber (6¹, 6²) for dilating
30 said balloon chamber (6¹, 6²) in the operational attached position.

6. A device according to claim 5 characterized in that a centrally located locking mechanism (14) is arranged to mutually interconnect both balloon chambers (6^1 , 6^2) at their central part (13).

5 7. A device according to claim 6, characterized in that the locking mechanism (14) is divided into two with each respective member (14A, 14B) attachable to the outer wall (6C, 6D) of the respective balloon chamber (6^1 , 6^2) for example as snap together members.

10 8. A device according to claim 4, characterized in that a number of threads (151) are arranged to twist sideways to form a circular shape and be locked in the twisted spring like position interconnecting the two balloon chambers against each other.

9. A device according to claim 1, characterized in that a
15 number of thin elastic threads, for example nitinol threads (151) are attached to a respective in axial direction (150, 152) relative to each other movable holder nucleus (153, 154) and that the threads (151) are arranged to twist sideways and then to assume a circular shape and with means for closing said
20 passage.

10. A device according to claim 9, characterized in that the threads (151) are attached with different inclination (x , y) with reference to the respective holder nucleus (156, 157) at which the threads (151) are forced to be directed towards that
25 holder nucleus (157) from which the threads (151) depart with the largest angle (y) calculated from the centre axis (158) of the holder nuclei.

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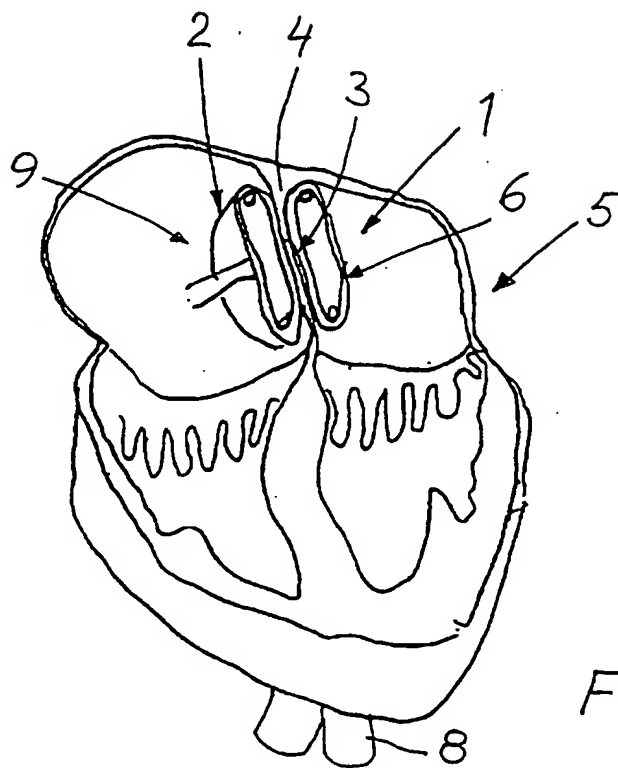


FIG. 1

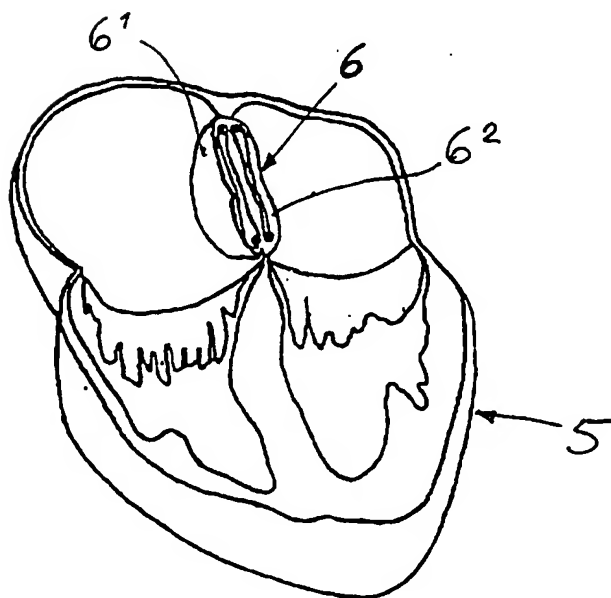


FIG. 2

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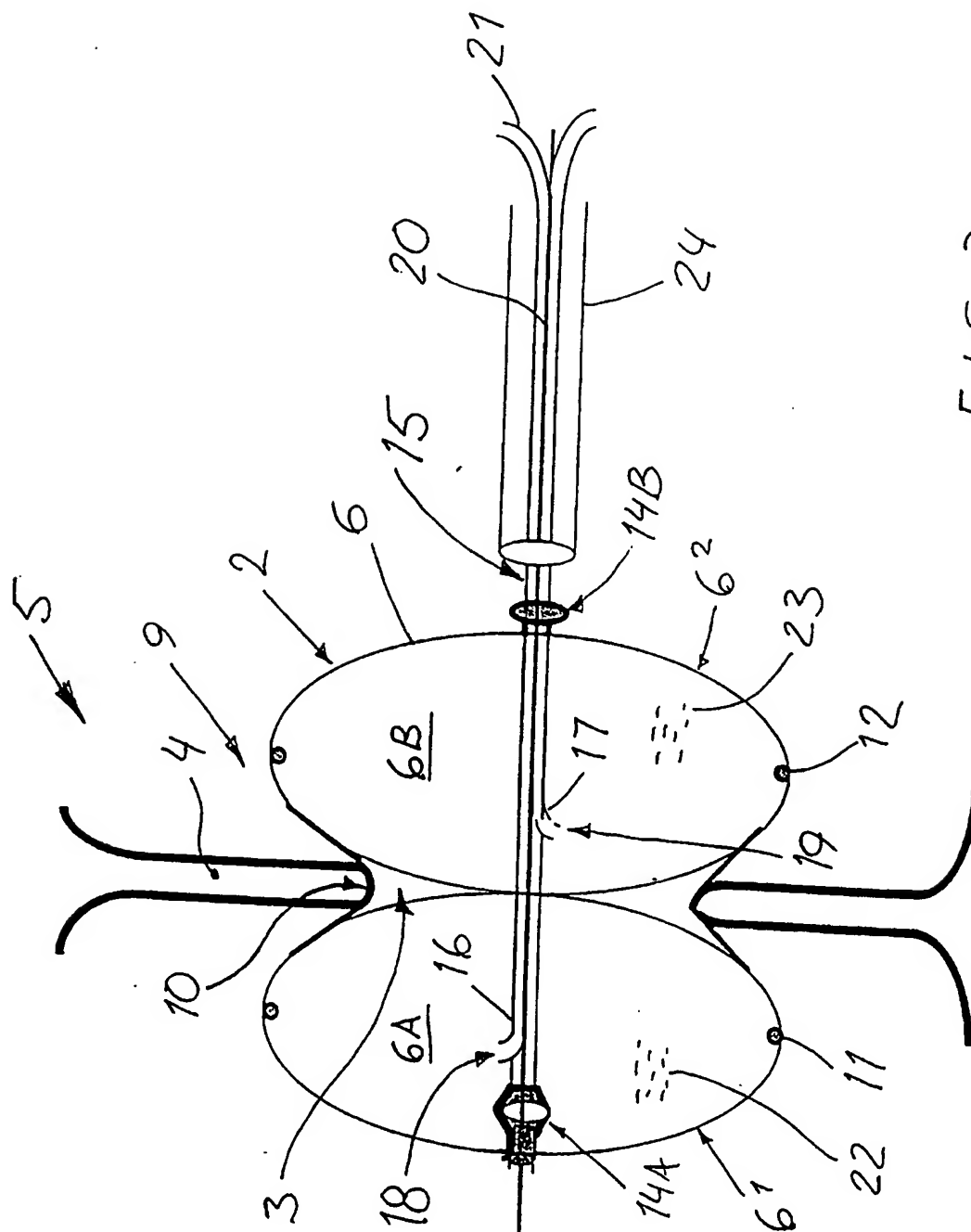


FIG. 3

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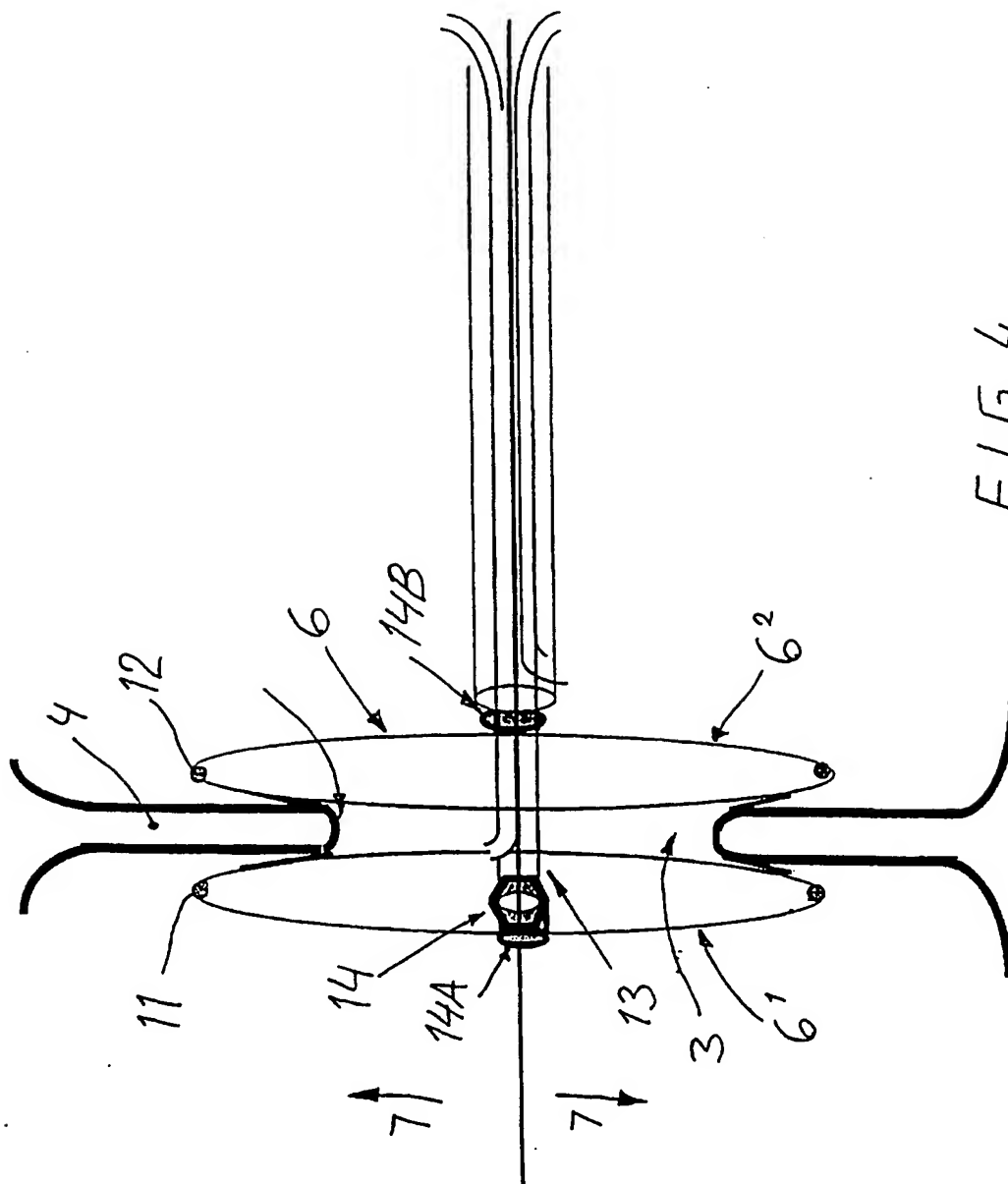


FIG. 4

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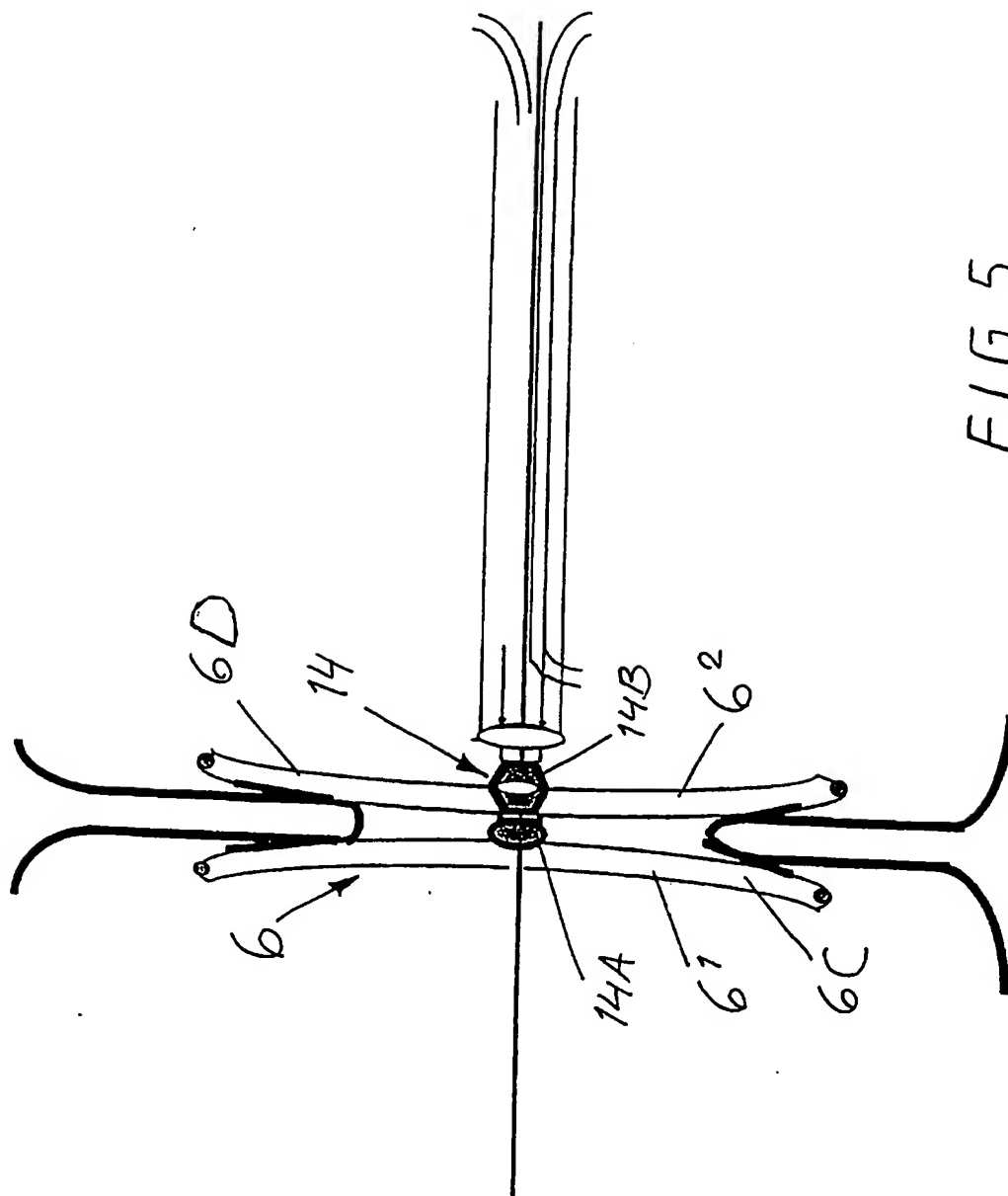


FIG. 5

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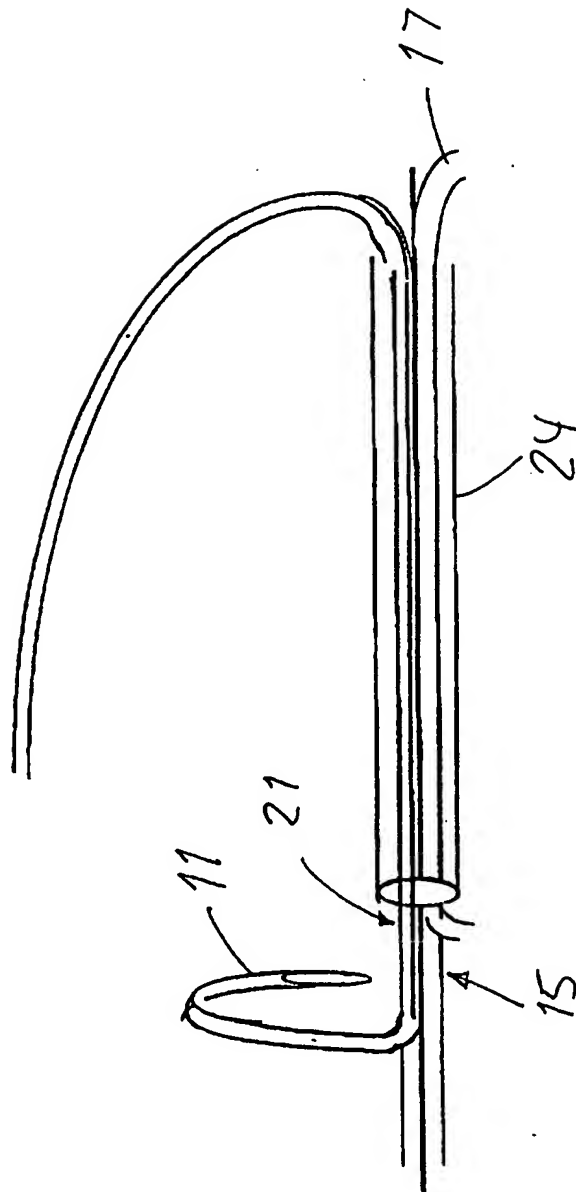


FIG. 6

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FIG. 7

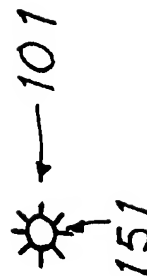
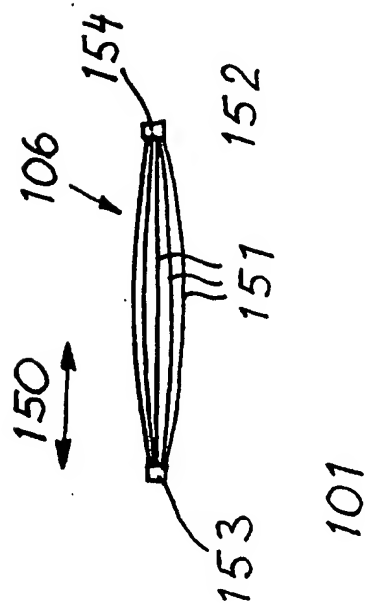


FIG. 8

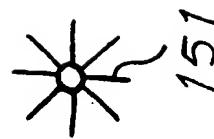
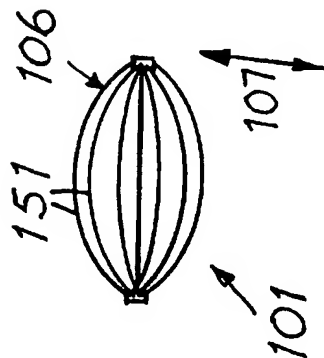
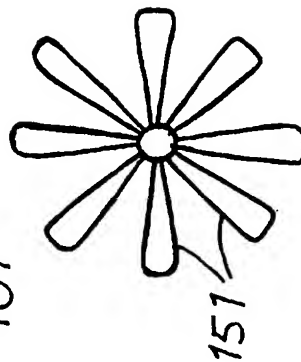
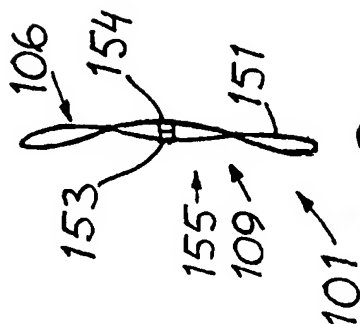


FIG. 9



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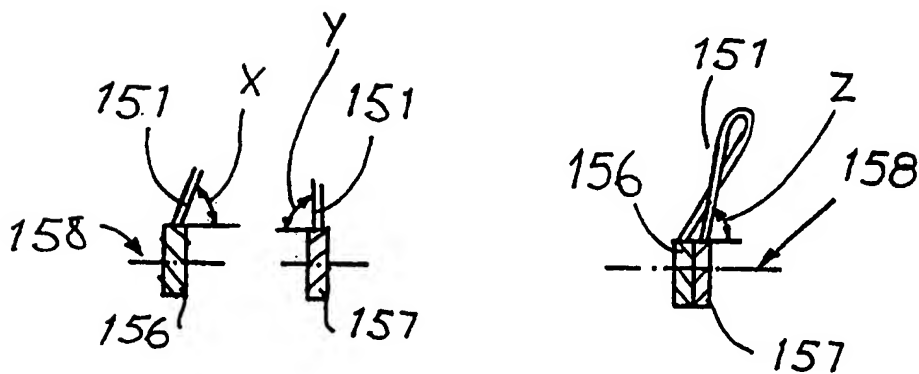
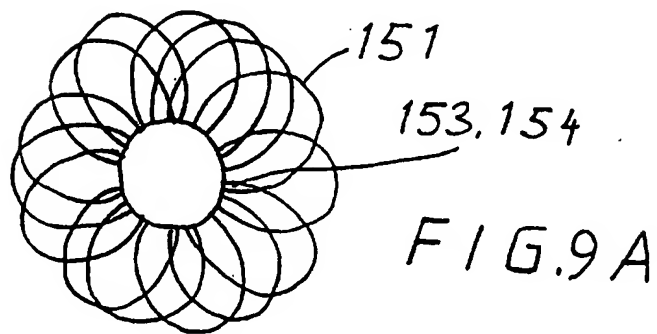
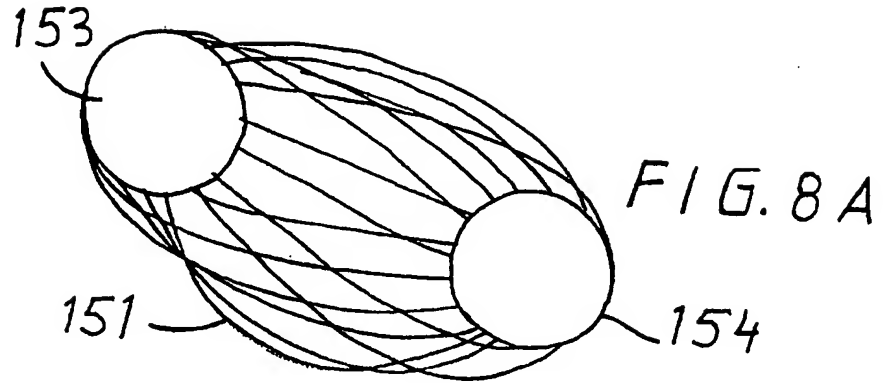


FIG. 10

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/00747

A. CLASSIFICATION OF SUBJECT MATTER		
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C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 2514142 A1 (ALTON OCHSNER MEDICAL FOUNDATION), 14 October 1976 (14.10.76), page 13 - page 14, figure 9 --	1
X	DE 2822603 A1 (THIERFELDER KAY), 29 November 1979 (29.11.79), page 10, figures 4-6 --	1,9,10
X	FR 2714284 A1 (PETITIER HUBERT ET AL.), 30 June 1995 (30.06.95), page 8, line 10; page 9, line 7 - page 10, line 2, figures 1-3 --	1-4
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18 Sept. 1997		23 -09- 1997
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4836204 A (R.W. LANDYMORE ET AL.), 6 June 1989 (06.06.89), column 3, line 35 - column 4, line 30, figure 1 ----- -----	1-3

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/09/97

International application No.
PCT/SE 97/00747

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
DE	2514142	A1	14/10/76	AU 489252 B	23/10/76
				FR 2305165 A,B	22/10/76
				GB 1509023 A	26/04/78
				US 3874388 A	01/04/75

DE	2822603	A1	29/11/79	NONE	

FR	2714284	A1	30/06/95	NONE	

US	4836204	A	06/06/89	NONE	

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